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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,540	09/05/2003	Steve Koh	A03P1060	8767

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PACESETTER, INC.  
15900 VALLEY VIEW COURT  
SYLMAR, CA 91392-9221

EXAMINER
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FLORY, CHRISTOPHER A

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3762

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/656,540	<b>Applicant(s)</b> KOH ET AL. <span style="float: right;">CT</span>	
	<b>Examiner</b> Christopher A. Flory	<b>Art Unit</b> 3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7,8,15,17,21,23,25,26 and 29-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7,8 and 25 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,15,17,21,23,26 and 29-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 4, 5, 15-17, 21, 23, 26, 31 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Thornander et al. in view of Warner et al., "Beat-by-Beat Modulation..." (hereinafter referred to as Warner and Loeb; for full citation, see page 2 of the IDS submitted by Applicant on 5 September 2003).

Regarding claims 1, 2 and 15, Thornander et al. discloses a method comprising delivering one or more pacing pulses to an atrium (ABSTRACT; column 2, line 67 through column 3, line 7); determining one or more atrioventricular conduction interval times based on the pacing pulses (ABSTRACT; column 3, lines 37-45); and determining a respiratory characteristic based at least in part on the AV conduction interval times (column 21, line 65 through column 22, line 10; column 23, lines 7-8; column 2, lines 47-51; column 3, lines 20-30; column 3, lines 65-68).

It is noted that increased workload and changes in heart rate as disclosed in Thornander et al. are being understood as respiratory characteristics, because increased workload (i.e. exercise) produces an increased respiratory frequency, while it is known that heart rate is an indicator of respiratory state, since inhalation raises the instantaneous heart rate slightly, while exhalation decreases instantaneous heart rate.

Further regarding claims 1, 2 and 15, and regarding claim 7, Thornander et al. discloses the instant invention substantially as claimed except that the respiratory cycle length is determined based on the atrioventricular conduction interval times. In the same field of endeavor, Warner and Loeb teaches that AV interval shows a 1-to-1 correlation to the respiratory cycle length both with and without pacing (page 1127, col.2, paragraph 4 through page 1128, end of column 2; p. 1131, col. 2, paragraph 1; Fig. 1). It follows that a change or trend in AV conduction interval times would be sufficient to determine a relative respiratory cycle length. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Thornander et al. to determine respiratory cycle length based on a comparison of AVIs as disclosed in Warner and Loeb since it has been shown in Warner and Loeb that a change in respiratory cycle length correlate in a 1-to-1 manner to a specific change in AV conduction interval times and vice versa.

Regarding claim 4, Thornander et al. discloses that the atrial pacing occurs at a rate that varies with respect to an intrinsic rate (ABSTRACT; column 2, line 47 through column 3, line 6).

Regarding claim 5, the pacemaker of Thornander et al. varies the atrial pacing rate in response to intrinsic rates that change over a given time period based on increased or decreased physiologic demands. Because the rates on which the pacing is based vary with respect to time, the atrial pacing rate can also be said to vary with respect to time. Therefore, the claim limitation of the instant claim does not distinguish over the prior art.

Regarding claims 21, 23 and 26, Thornander et al. shows an implantable cardiac stimulation system (Fig. 10, pacemaker 16) comprising sensing circuitry operative to sense atrial and ventricular events (P-wave sense/pace amp 48, R-wave sense/pace amp 56); a processor connected to the sensing circuitry (Fig. A-1, microprocessor 408) operative to determine one or more A-V conduction interval times based on the delivered stimulation pulses (ABSTRACT; column 3, lines 37-45) and further operative to determine a respiratory characteristic based at least in part on the A-V interval times (column 21, line 65 through column 22, line 10; column 23, lines 7-8; column 2, lines 47-51; column 3, lines 20-30; column 3, lines 65-68); and further comprising a pulse generator operative to generate stimulation pulses for delivery to a patient's heart (Fig 10, pulse generator logic 42 and pulse output driver circuits 44 connected to heart 18), and at least one electrode (atrial lead 22 with tip electrode 24; ventricle lead 30 with electrode 46).

3. Claim 3 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Thornander et al. in view of Warner and Loeb, and further in view of Applicant's own admitted prior art (Admission).

Thornander et al. discloses the instant invention substantially as claimed but does not expressly state that atrial pacing occurs at a frequency that is at least double the respiratory frequency. Admission teaches that according to signal sampling theory, the sampling frequency must be greater than twice the maximum frequency of the sampled behavior in order to sufficiently avoid frequency aliasing (paragraph [68]). In this case, this theory applies in that the AV Interval, which represents the sample of the respiratory characteristic, must be calculated at greater than double the frequency of the respiratory cycle, which inherently means that atrial pacing must occur at double the respiratory frequency (because one AV Interval is sampled for each atrial pacing pulse delivered). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system disclosed in Thornander et al., with the pacing frequency of at least double the respiratory frequency in Admission, for the advantage of avoiding frequency aliasing and the resultant of improper determination of the respiratory characteristic (motivation to combine provided by Admission, paragraph [68]).

Regarding claims 31 and 32, it is noted that the respiratory cycle length is being determined based on AVI, which is itself based on heart rate, which is an inherently cyclical pattern.

4. Claims 29 and 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Thornander et al. in view of Warner and Loeb as applied to claim 1 above, and further in view of Cho et al. (US 2005/0119711, hereinafter Cho'711).

Regarding claims 29 and 30, Thornander et al. in view of Warner and Loeb discloses the invention substantially as claimed, but does not expressly disclose that normal respiration be indicated by a substantially cyclical interval pattern, and that abnormal respiration be indicated by absence of a cyclical interval pattern. In the same field of endeavor, Cho'711 teaches that normal breathing is typically indicated by heart rate cycles (i.e. a cyclical interval pattern) of less than 25 seconds, whereas apnea-hyperapnea cycles are represented by heart rate cycles of 40-80 seconds, i.e. an absence of the 25 second cyclic pattern of normal sleep. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Thornander et al. with the cyclic pattern recognition indicative of normal and abnormal respiration as taught by Cho'711 to provide the Thornander et al. system with the same advantage of discriminating between normal and apnea-hyperapnea breathing.

5. Claims 15, 16, 21, 23 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lurie et al. in view of Warner and Loeb.

Regarding claims 15 and 16, Lurie et al discloses a method comprising determining one or more A-V conduction interval times and determining a respiratory characteristic based at least in part on the one or more conduction interval times (ABSTRACT; column 2, lines 24-38; Figures 3-6); wherein the respiratory characteristic comprises a respiratory cycle length (column 2, line 31—respiration rate is being taken by definition to be a well-known mathematical equivalent to respiratory cycle length,

because a patient with a respiration rate of 10 breaths per minute has with mathematical certainty a respiratory cycle length of 6 seconds).

Regarding claims 21, 23 and 26, Lurie et al. shows an implantable cardiac stimulation system (Fig. 1, device 10) comprising sensing circuitry (sense amp 36, lead 12); a processor connected to the sensing circuitry (microprocessor 22); and further comprising a pulse generator (pacing pulse generator 38), and at least one electrode connected to the pulse generator (electrodes 14 on heart 16).

Lurie et al. discloses the instant invention substantially as claimed except for determining whether the respiratory characteristic (respiratory cycle length) indicates apnea. In the same field of endeavor, Warner and Loeb teaches that AV interval shows a 1-to-1 correlation to the respiratory cycle length both with and without pacing (page 1127, col.2, paragraph 4 through page 1128, end of column 2; p. 1131, col. 2, paragraph 1; Fig. 1). It follows that a change or trend in AV conduction interval times would be sufficient to determine a relative respiratory cycle length. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Thornander et al. to determine respiratory cycle length based on a comparison of AVIs as disclosed in Warner and Loeb since it has been shown in Warner and Loeb that a change in respiratory cycle length correlate in a 1-to-1 manner to a specific change in AV conduction interval times and vice versa.

***Allowable Subject Matter***

6. Claims 7, 8 and 25 are allowed.

***Response to Arguments***

7. Applicant's arguments filed 13 December 2007 have been fully considered but they are not persuasive. Claims 1, 2, 4, 5, 15-17, 21, 23, 26, 31 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Thornander et al. in view Warner and Loeb. Claims 15, 16, 21, 23 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lurie et al. in view of Warner and Loeb.

Regarding claims 1 and 15, Applicant argues that Warner and Loeb fails to teach the claim limitation of comparing AV intervals to detect an interval pattern indicative of either normal respiration or abnormal respiration, but rather teaches determining a respiratory cycle length based on AV conduction intervals. It is noted that the respiratory cycle length is considered an interval pattern indicative of normal or abnormal respiration, given that cycle respiratory implies respiration, cycle implies a pattern, and length implies an interval. It is noted that respiratory cycle length will clearly be shorter than normal in cases of abnormal respiration such as hyperventilation, and longer than normal respiration in cases of abnormal respiration such as apnea.

Applicant puts forth the same arguments in regards to claims 21 and 23, which are not persuasive for similar reasoning.

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3762

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory  
21 January 2008

**/George Manuel/**  
Primary Examiner